



EUCERD Core Recommendations on Rare Disease Patient Registration and Data Collection

Executive Summary

On 5 June 2013, during the eighth meeting of the European Union Committee of Experts on Rare Diseases, the *EUCERD Core Recommendations on Rare Disease Patient Registration and Data Collection* were unanimously adopted by the 51-member EUCERD. This Recommendation is the fruit of various multi-stakeholder meetings, consultations of the EUCERD and previous publications in the field.

Rare disease registries are valuable instruments for increasing knowledge on rare diseases, and for supporting fundamental, clinical and epidemiological research, as well as for post-marketing surveillance of orphan medicinal products and medicines used off-label. This data is also crucial for the planning of healthcare services.

The Council Recommendation on an Action in the Field of Rare Diseases (2009/C 151/02) (8 June 2009) cites registries as a source of information on rare diseases and encourages this resource to be supported at Member State and Community level. Registries and data collection for rare diseases are also key aspects of the national plans/strategies for rare diseases currently being elaborated/implemented at Member State level, as encouraged by the Council Recommendation.

The *EUCERD Core Recommendations on Rare Disease Patient Registration and Data Collection* cover six main aspects on which a consensus has been reached by stakeholders in relation to patient registries and data collection.

Firstly, the recommendation calls for the international operability of registries and databases, primarily by use of appropriate coding systems and core data sets to enable the necessary pooling of data for public health and research purposes. The recommendation then sets down guiding principles concerning the establishment of registries and collection of data, highlighting the various sources and uses of patient data as well as how to best share this information. The document also underlines the importance of adherence to good practice guidelines in the field, particularly concerning multi-stakeholder participation across all aspects of registry design and governance. It is highlighted that registries should be flexible so as to adapt to meet future needs. Finally, the recommendation emphasises the importance of sustainability for the time span of the registry's utility, and encourages public-private partnerships as a long-term model for optimisation of resources, sustainability and co-creation of knowledge.



Now that a consensus on these aspects has been established in this recommendation, it is hoped that these recommendations will serve all stakeholders in the field, including Member States establishing their national plans/strategies for rare diseases and the European Commission services in their reflection on the sustainability of registries for rare diseases at European level. Indeed, the involvement of all stakeholders including policymakers, researchers, clinicians, industry and patients in designing, maintaining and governing registries is also called for by the recommendations.

The Recommendations are available on www.eucerd.eu here:

http://www.eucerd.eu/wp-content/uploads/2013/06/EUCERD_Recommendations_RDRRegistryDataCollection_adopted.pdf